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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,103	01/26/2001	Beatriz M. Carreno	GNN-009CP	7957

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EXAMINER

OUSPENSKI, ILIA I

ART UNIT PAPER NUMBER

1644

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/772,103	CARRENO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-11 and 13-24 is/are pending in the application.
- 4a) Of the above claim(s) 16-23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 and 15 is/are allowed.
- 6) ☒ Claim(s) 2-11, 13 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

*HL*

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/02/2005 has been entered.

2. Applicant's amendment, filed 02/02/2005, is acknowledged.

Claim 2 has been amended.

Claims 2 – 11 and 13 – 24 are pending.

Claims 16 – 23 have been withdrawn from further consideration by the Examiner as being drawn to non-elected invention.

*Claims 2 – 11, 13 – 15, and 24 are under consideration in the instant application.*

3. This Office Action will be in response to applicant's arguments, filed 02/02/2005.

The rejections of record can be found in the previous Office Action, mailed 02/02/2005.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

It is noted that New Grounds of Rejection are set forth herein.

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4. Given the absence of amendment or rebuttal to the objection of record, the specification stands objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 C.F.R. § 1.75(d)(1) and M.P.E.P. § 608.01(I).

Correction of the following is required:

Applicant is requested to identify the written support for amended claim 7, particularly the claimed limitation of "reduced binding of the antibody to the human CTLA4 with the substitution of amino acid 83."

Alternatively, Applicant is invited to amend the specification to provide proper antecedent basis for the claimed subject matter.

5. The disclosure stands objected to because of the following informalities: "Blanks" are present in the specification on pages 4, 5 and 28 for ATCC and hybridoma designations of the CTLA4 antibodies.

Applicant's request to hold correction in abeyance until such time as the ATCC designations can be provided is again acknowledged.

Appropriate correction is required but held in abeyance.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

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7. Claims 2 – 11, 13, and 24 are rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicant's amendment points to the specification at page 80, lines 3 – 19, and Figure 4a and 4b for support for the newly added limitation "wherein the antibody does not cause proliferation of a T cell". However, the specification does not appear to provide an adequate written description of the newly added limitation.

The specification at page 80, lines 3 – 19, states that antibody 26 was the only anti-CTLA4 antibody in the panel that was found to enhance proliferation of primary T cells. This statement does not provide that an anti-CTLA4 antibody which does not cause proliferation of a T cell is a part of the invention.

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

*Applicant is required to cancel the New Matter in the response to this Office Action.*

Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

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8. Claim rejection under **35 USC 102(e)** as being anticipated by Korman et al.:

Claims 2 – 7, 10, 11, 13, and 24 stand rejected under 35 USC 102(e) as being anticipated by Korman et al. (US 2002/0086014, of record, see entire document).

Applicant's arguments filed 02/02/2005 have been fully considered but were not found convincing.

Applicant argues that Korman et al. do not anticipate the amended claims, because the reference allegedly does not teach soluble monoclonal antibodies that do not cause proliferation of a T cell.

This is not found persuasive, because Korman et al. teach that multivalent anti-CTLA4 antibodies inhibit T cell proliferation (i.e. do not cause T cell proliferation; paragraph 0231), and exemplify multivalent anti-CTLA4 antibodies as IgM or IgA<sub>2</sub>, i.e. soluble classes of antibodies (paragraph 0232). Further, Korman et al. teach obtaining said antibodies by a genetic engineering approach, thus clearly pointing to the monoclonal nature of the antibodies (paragraph 0232). Thus Korman et al. explicitly teach soluble monoclonal antibodies that do not cause T cell proliferation.

Therefore, the rejection of record is maintained for the reasons of record, as they apply to the amended claims.

9. Claim rejection under **35 USC 102(e)** as being anticipated by Lowman et al.:  
Applicant's amendment has obviated the rejection of record.

However, it is noted that the rejection of record may be re-introduced upon cancellation of New Matter.

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10. Claim rejection under 35 USC 103(a) as being unpatentable over Korman et al. in view of Hamman et al.:

Claims 2 – 11, 13, and 24 stand rejected under **35 USC 103(a)** as being unpatentable over Korman et al. (US 2002/0086014, of record, see entire document) and further in view of Hamann et al. (US pat. No. 5,773,001, of record, see entire document).

Applicant's arguments filed 02/02/2005 have been fully considered but were not found convincing.

Applicant argues that the cited references do not teach or suggest all of the claimed limitations, because allegedly missing from these references is a soluble monoclonal antibody, as described in claim 2, that does not cause proliferation of a T cell.

This is not found persuasive, because, as discussed in detail in section 8 above, Korman et al. explicitly teach soluble monoclonal antibodies that do not cause T cell proliferation (paragraphs 0231 – 0232).

Therefore, the rejection of record is maintained for the reasons of record, as they apply to the amended claims.

11. Claim rejection under **35 USC 103(a)** as being unpatentable over Godfrey et al. and Kuchroo et al. in view of Hamann et al.: Applicant's amendment has obviated the rejection of record.

However, it is noted that the rejection of record may be re-introduced upon cancellation of New Matter.

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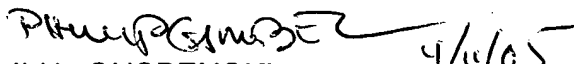
**12. Conclusion: No claim is allowed.**

*Claims 14 and 15 appear to be allowable.*

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-2920.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
ILIA OUSPENSKI  
Patent Examiner  
Art Unit 1644  
4/11/05  
PHILLIP GAMBEL, PH.D  
PRIMARY EXAMINER  
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April 8, 2005